

**UNITED STATES DEPARTMENT OF COMMERCE****Patent and Trademark Office**Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

08/944,850 10/06/97 WALT

D TU-97-01

MM92/0228

FLEHR HOHBACH TEST
ALBRITTON & HERBERT LLP
FOUR EMBARCADERO CTR STE 3400
SAN FRANCISCO CA 94111-4187

EXAMINER

HANNAHER, C

ART UNIT	PAPER NUMBER
----------	--------------

2878

DATE MAILED:

02/28/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)
	08/944,850	WALT ET AL.
	Examiner Constantine Hannaher	Art Unit 2878

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 14 September 2000 and 02 November 2000.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 39-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 39-48 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) Notice of References Cited (PTO-892)
- 16) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 25.
- 18) Interview Summary (PTO-413) Paper No(s) _____.
- 19) Notice of Informal Patent Application (PTO-152)
- 20) Other: _____

DETAILED ACTION**Information Disclosure Statement**

1. Where the IDS citations are submitted but not described, the examiner is only responsible for cursorily reviewing the references. The initials of the examiner on the PTO-1449 indicate only that degree of review unless the reference is either applied against the claims, or discussed by the examiner as pertinent art of interest, in a subsequent office action. See Guidelines for Reexamination of Cases in View of *In re Portola Packaging, Inc.*, 110 F.3d 786, 42 USPQ2d 1295 (Fed. Cir. 1997), 64 FR at 15347, 1223 Off. Gaz. Pat. Office at 125 (response to comment 6).

2. As set forth in MPEP § 609:

37 CFR 1.98(b) requires that each U.S. patent listed in an information disclosure statement be identified by patentee, patent number, and issue date. Each foreign patent or published foreign patent application must be identified by the country or patent office which issued the patent or published the application, an appropriate document number, and the publication date indicated on the patent or published application. Each publication must be identified by author (if any), title, relevant pages of the publication, date and place of publication. The date of publication supplied must include at least the month and year of publication, except that the year of publication (without the month) will be accepted if the applicant points out in the information disclosure statement that the year of publication is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the particular month of publication is not in issue. The place of publication refers to the name of the journal, magazine, or other publication in which the information being submitted was published.

Since this quotation from the MPEP was included in the Office action mailed April 12, 2000, the failure of applicant to either supply a month of publication or to point out in the statement that the year of publication is sufficiently earlier so that the particular month is not in issue cannot be considered a matter of inadvertence. The information disclosure statement submitted December 27, 2000 denies any availability and this creates such an issue.

3. The errors in the information disclosure statement (regarding the appropriate document number of the published foreign patent application published in January of 2000) cannot be considered a matter of inadvertence in view of the presence of the INID codes on the document(s), see MPEP § 901.05(b).

Claim Objections

4. The “elements” of dependent claim 41 are presumed to find their antecedent basis in the first and second sensor elements of independent claim 39, lines 3 and 4.

5. The “sensor elements” of dependent claims 43 and 44 are presumed to find their antecedent basis in the first and second sensor elements of independent claim 39, lines 3 and 4.

Claim Rejections - 35 USC § 112

6. Claims 39-48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The presence of the text “at least” in clause (i) of the providing step (a) of sole independent claim 39 is indefinite, as it is unclear whether the presence of any other subpopulation is a necessary element of the method, despite the presence of a second in clause (ii), especially since another subpopulation is not referred to again in claims 39 and 41-48. The balance of the claims is rejected on the basis of their dependence.

Claim Rejections - 35 USC § 102

7. Claims 39, 40, 43-45, 47, and 48 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Pinkel *et al.* (US005690894A).

With respect to independent claim 39, Pinkel *et al.* discloses an assay method corresponding to the disclosed apparatus (Fig. 4) which comprises a sensor array 14 having at least two

subpopulations (the groups of strands **10**) of different sensor elements (sensor ends **11**, where each group may have a different sensor, column 8, lines 50-67). The assay method would comprise the steps of providing the sensor array **14**, adding a sample **30** comprising a first target analyte that binds to the first sensor elements (*e.g.*, first collection **25**), measuring first fluorescence signals (column 13, lines 33-39) of at least two of the sensor elements **11** of the first subpopulation (group) with detector **20**, and summing the first fluorescence signals (column 9, lines 12-14 and 21-25).

With respect to dependent claim 40, the method suggested by Pinkel *et al.* further comprises adding a sample **30** comprising a second target analyte that binds to the second sensor elements (*e.g.*, second collection **26**), measuring second fluorescence signals (column 13, lines 33-39) of at least two of the sensor elements **11** of the second subpopulation (group) with detector **20**, and summing the second fluorescence signals (column 9, lines 12-14 and 21-25).

With respect to dependent claim 43, the sensor elements (ends **11**) in the method of Pinkel *et al.* comprise chemical functional groups (column 10, lines 28-34).

With respect to dependent claim 44, the sensor elements (ends **11**) in the method of Pinkel *et al.* may comprise oligonucleotides in view of column 10, lines 56-63 and column 3, line 13.

With respect to dependent claim 45, the first target analyte in the method of Pinkel *et al.* is an oligonucleotide (column 4, line 65 to column 5, line 1).

With respect to dependent claim 47, the increase in signal-to-noise ratio using the method of Pinkel *et al.* is inherent in (necessarily follows from) the identity of the apparatus and method of operation.

With respect to dependent claim 48, the sensor array **14** provided in the method of Pinkel *et al.* comprises a fiber optic bundle.

Claim Rejections - 35 USC § 103

8. Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pinkel *et al.* (US005690894A).

With respect to dependent claim 46, it would have been obvious to one of ordinary skill in the art at the time the invention was made to adjust the baseline of fluorescence signals in the method of Pinkel *et al.* because the detector system may be employed with a computerized data acquisition system and analytical program (column 12, lines 10-22) and such an adjustment (calibration) is a known and useful step in accurately measuring responses.

9. Claims 41 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pinkel *et al.* (US005690894A) in view of Lough *et al.* (US005900481A).

With respect to dependent claim 41, the sensor elements in the method of Pinkel *et al.* do not comprise beads, but are instead the ends **11** of the fiber strands **10** which may have a specific shape (column 7, line 56 to column 8, line 3). Lough *et al.* shows that beads are known (Fig. 1) as elements in a sensor array (column 5, lines 62-67). The beads of Lough *et al.* are suitable for the types of binding molecules used and fluorescent signals measured in the sensor array **14** of Pinkel *et al.* and further provide the convex surface Pinkel *et al.* identifies as advantageous. Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Pinkel *et al.* to specify that the sensor ends **11** therein were bound to beads as suggested by Lough *et al.* (as the fiber strands **10** in Pinkel *et al.* qualify as a support as described by Lough *et al.* at column 3, line 29).

With respect to dependent claim 42, the sensor elements in the method of Pinkel *et al.* do not comprise beads, but are instead the ends **11** of the fiber strands **10** which may have a specific shape (column 7, line 56 to column 8, line 3). Lough *et al.* shows that beads are known (Fig. 1) as

elements in a sensor array (column 5, lines 62-67). The beads of Lough *et al.* are suitable for the types of binding molecules used and fluorescent signals measured in the sensor array **14** of Pinkel *et al.* and further provide the convex surface Pinkel *et al.* identifies as advantageous. Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Pinkel *et al.* to specify that the sensor ends **11** therein were bound to beads as suggested by Lough *et al.* (as the fiber strands **10** in Pinkel *et al.* qualify as a support as described by Lough *et al.* at column 3, line 29). The connection of the beads suggested by Lough *et al.* and the sensor ends **11** in the sensor array **14** provided in the method suggested by Pinkel *et al.* is a choice within the ordinary skill in the art at the time the invention was made. The specification of "wells" would have been obvious in view of the mechanical advantage afforded thereby in retaining the suggested beads to the faces of the fiber optic strands **10** and the knowledge from Lough *et al.* at column 3, lines 35-37 that beads in pits (functionally equivalent to the recited wells) are known.

Response to Submission(s)

10. The amendment filed November 2, 2000 has been entered.
11. "Responsive to amendment of November 2, 2000 and supplemental to the action mailed November 13, 2000." See M.P.E.P. § 714.05.

The following portions of the previous action are to be disregarded:

Paragraphs 3, 5, 8, and 9.

The period for reply runs from the date of the mailing of this supplemental action.

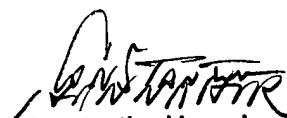
Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Constantine Hannaher whose telephone number is (703) 308-4850. The examiner can normally be reached on Monday-Friday with flexible hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Seungsook (Robin) Ham can be reached on (703) 308-4090. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7722 for regular communications and Not Established for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0956.

ch
February 27, 2001



Constantine Hannaher
Primary Examiner